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Dated: January 19, 2011
Electronic Signature for: Brian C. Trinqué, Ph.D.: / Brian C. Trinqué, Ph.D./

Docket No.: EISN-018CPRCE
(PATENT)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of:
Kenichi Chiba *et al.*

Application No.: 10/657,910

Confirmation No.: 5169

Filed: September, 9, 2003

Art Unit: 1625

For: MACROCYCLIC COMPOUNDS USEFUL AS
PHARMACEUTICALS

Examiner: T. Oh

MS Issue Fee
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

STATEMENT UNDER 37 CFR § 1.705(b)(2)

Dear Sir or Madam:

1. This statement is respectfully submitted in support of the “Application for Patent Term Adjustment Including Request for Reconsideration Under 37 CFR §1.705(b)” for the above-referenced application. In view of the following, it is respectfully requested that Applicants be granted a minimum patent term adjustment of **531 days**.

2. The patent term adjustment as shown on the face of the Notice of Allowance, mailed on October 19, 2010 is 0 days. A copy of the PTO’s Patent Term Adjustment calculation (“PTA Sheet”) available on PAIR is also submitted herewith as Appendix A. Applicants respectfully submit that the determination of 0 days of patent term adjustment is incorrect for the reasons discussed below.

3. The factual bases for the above adjustment are set forth as follows:

A. Examination Delays Pursuant to 37 CFR §1.702 and §1.703

Pursuant to 37 CFR §1.703(f), the period of adjustment of the term of the patent under §1.702 is the sum of the periods of examination delay calculated under subparagraphs (a)-(e), to the extent that such periods are not overlapping, less the sum of the periods calculated under §1.704 (the period of Applicant Delay). In the above-referenced application, Applicants are entitled to a period of examination delay equal to the sum of the periods of delay under §1.703(a) and (b) for the reasons set forth below.

(i) “14 Month Delay” Pursuant to §1.703(a)(1)

In accordance with 37 CFR §1.703(a)(1), Applicants are entitled to a period of patent term adjustment due to the failure by the Office to mail an action under 35 U.S.C. 132 not later than 14 months after the date on which the application was filed under 35 U.S.C. 111(a) (*i.e.*, September 9, 2003).

Accordingly, Applicants are entitled to a period of patent term adjustment beginning November 9, 2004 and ending on January 26, 2005, the date of mailing of the non-final rejection that was ultimately entered in the application. As such, the period of patent term adjustment due to the 14 Month Delay by the Office is **78 days**.

(ii) “Four Month Delay” Pursuant to §1.703(a)(2)

In accordance with 37 CFR §1.703(a)(2), Applicants are entitled to a period of patent term adjustment due to the failure by the Office to respond to a reply under 35 U.S.C 132 not later than 4 months after the date on which the reply was filed. Applicants replied to a non-final office action on August 1, 2005. The Office responded with a non-final office action of March 16, 2006.

Accordingly, Applicants are entitled to a period of patent term adjustment beginning December 5, 2005 and ending on March 16, 2006. As such, the period of patent term adjustment due to the 4 Month Delay by the Office is **105 days**.

(iii) “Three Years Delay” Pursuant to 37 CFR §1.703(b)

The USPTO’s Determination of Patent Term Adjustment Under 35 U.S.C. 154(b) mailed on October 19, 2010 states that “[i]f the issue fee is paid on the date that is three months after the mailing date of this notice and the patent issues on the Tuesday before the date that is 28 weeks (six and a half months) after the mailing date of this notice, the Patent Term Adjustment will be 0 day(s).” Applicants assert that this statement by the USPTO is not correct.

The Office did not comply with the requirement of 35 U.S.C. 154(b) and 37 CFR §1.702(b), which requires issuance of a patent within 3 years after the date on which the national stage commenced under 35 U.S.C. 371(b). In accordance with 37 CFR §1.703, Applicants have calculated a maximum period of Three Years Delay (based on the above USPTO statement) beginning on the day after the date that is three years after the date on which the above-referenced patent was filed (*i.e.*, September 9, 2003), and ending on the date that the patent is expected to issue. The Notice of Allowance states that the patent is expected to issue on the Tuesday immediately preceding the date that is 28 weeks from the mailing date of the Notice of Allowance. In this instance, the date that is 28 weeks from the mailing date of the Notice of Allowance is Tuesday, May 5, 2011. Therefore, our calculation is based on an expected issue date of May 5, 2011. Accordingly, the period of Three Years Delay is at least equal to the sum of the number of days in the period beginning on September 10, 2006 and ending on May 5, 2011. This period of delay is 1697 days. Applicants reserve the right to pursue additional Patent Term Adjustment if, for example, the patent issues after May 3, 2011.

Pursuant to 37 CFR §1.703(b)(4), a period of time is excluded from the Three Years Delay which begins on the date on which a notice of appeal is filed (*i.e.*, May 7, 2009) and ends on the date of mailing of a notice of allowance (*i.e.*, October 19, 2010). This period of delay is 531 days.

Pursuant to 37 CFR §1.703(b)(1), a period of time is excluded from the Three Years Delay which begins on the date on which a request for continued examination is filed (*i.e.*, October 23, 2009) and ends on the date that the patent was issued (*i.e.*, May 3, 2011). This period of delay is 558 days.

The sum of non-overlapping periods of exclusion pursuant to §1.703(b)(4) and §1.703(b)(1) are 727 days (531 days + 558 days – 362 days of overlap). Accordingly, the net period of Three Years Delay is 1697 days - 727 days, *i.e.*, **970 days**.

(iv) Calculation of Total Period of Examination Delay Pursuant to 37 CFR §1.703(f)

As set forth in 37 CFR §1.703(f), the period of examination delay based on the grounds set forth in 37 CFR §1.702 is the sum of the period of 14 Month Delay (78 days, ending January 26, 2005), and the period of 4 Month Delay (105 days, ending March 16, 2006), and the period of Three Years Delay (970 days, beginning on September 10, 2006). These periods of delay do not overlap. Accordingly, the total examination delay is **1153 days**.

B. “Applicant Delay” Pursuant to 37 CFR §1.704

Pursuant to 37 CFR §1.704, the period of adjustment of the term of the patent due to examination delay is reduced by the period of Applicant Delay. Applicants submit that the correct period of Applicant Delay is **622 days**.

Applicants note that a response to the Office Action mailed on January 26, 2005 was sent to the Office on July 26, 2005, and not on August 26, 2005 as is indicated on the PAIR PTA sheet. Accordingly, Applicants thereby incurred a delay of 91 days.

C. Calculation of Correct Patent Term Adjustment Pursuant to 37 CFR §1.702(f)

As set forth in 37 CFR §1.703(f), Applicants are entitled to a period of patent term adjustment equal to the period of Examination Delays reduced by the period of Applicant Delay (*i.e.*, 1153 days – 622 days = 531 days). Therefore, Applicants submit that the correct patent term adjustment for the above-referenced application is **531 days**.

4. In accordance with 37 CFR§1.705(b)(2)(iii), Applicants submit that the present application is subject to a terminal disclaimer over U.S. Patent No. 7,799,827.

Dated: January 19, 2010

Respectfully submitted,

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